JUL 12 2011

K111397

510(k) Summary

ArthroCare Corporation
Titan™ Ti Suture Anchor System

General Information

Submitter Name/Address:

ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number:

2951580

Contact Person:

Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936
(408) 735-6426

Date Prepared:

May 18, 2011

Device Description

Trade Name:

- 5.5mm Titan Ti Suture Anchor with #2 MagnumWire with Needles
- 5.5mm Titan Ti Suture Anchor with #2 MagnumWire
- 6.5mm Titan Ti Suture Anchor with #2 MagnumWire with Needles
- 6.5mm Titan Ti Suture Anchor with #2 MagnumWire
- Titan Bone Punch
- Titan Removal Tool Driver
- Titan Removal Tool Capture Sleeve

Generic/Common Name:

Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)

Classification Name:

Class II, 21 CFR 888.3040
Product Code MBI

Predicate Devices

Arthrocare Titan Ti Suture Anchor	K092133 (11/5/2009)
Arthrocare Titan Ti Suture Anchor System	K101184 (5/18/2010)

K111397

Product Description

The ArthroCare Titan Ti Suture Anchor is a fully-threaded, self-tapping, titanium corkscrew shape anchor available in 5.5mm and 6.5mm diameter sizes. The suture anchor comes preconfigured with MagnumWire® sutures and is mounted on a disposable delivery driver The device is supplied sterile and is available with or without needles. The optional Titan instruments are used to facilitate implantation and removal of the Titan Ti Suture Anchor

Intended Uses/Indications for Use

The Titan Ti Suture Anchor System is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist and elbow in the following procedures:

- Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament/Tendon Repair, Bunionectomy;
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodosis;
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction;
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair;
- Hip: Capsular Repair, Acetabular Labral Repair

Substantial Equivalence

The Titan Ti Suture Anchor system design and technology is substantially equivalent to the existing Titan Ti Suture Anchor devices cleared in K101184 and K092133 The addition of polyethylene tubing to improve shaft design does not raise new questions regarding the safety and effectiveness of the Titan Ti Suture Anchor system. The proposed system is safe and effective as the predicate device.

Summary of Safety and Effectiveness

The proposed modifications to the Titan Ti Suture Anchor System are not substantial changes, and do not significantly affect the safety or efficacy of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ArthroCare Corporation
% Ms.Valerie Defiesta
Regulatory Affairs Director
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

JUL 12 2011

Re: K111397
Trade/Device Name: Titan Ti Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 30, 2011
Received: July 1, 2011

Dear Ms. Defiesta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111397

Device Name: ArthroCare® Titan™ Ti Suture Anchor System

Indications for Use:

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- Hip: Capsular Repair, Acetabular Labral Repair

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-the-Counter Use (21 CFR 807 Subpart C)	____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111397